VERMONT

Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
October 20, 2015

Board Members:
Present:

Zail Berry, MD
Clayton English, PharmD
Mark Pasanen, MD
Louise Rosales, NP
Michael Biddle, PharmD
Jaskanwar Batra, MD
James Marmar, RPh
Joseph Lasek, MD, Chair
Patrica King, MD

Absent:
Janet Farina, RPh

Staff:
Michael Ouellette, RPh, GHS/Emdeon
Jeff Barkin, MDGHS/ Emdeon
Nancy Hogue, PharmD, DVHA
Stacey Baker, DVHA
Carrie Germaine, DVHA
Mary Beth Bizzari, RPh, DVHA
Daljit Clark, DVHA
Aaron French, DVHA
Jason Pope, DVHA
Laurie Pedlar, RPh, GHS/Emdeon
Thomas Simpatico, MD, DVHA
Scott Strenio, MD, DVHA
George Thabault, DVHA

Guests:
Rita Baglini, APS Health Care
John Belviso, Boehringer Ingelheim
Kristen Bruno-Doherty, AstraZeneca
Adam Denman, GSK
Maggie Glassman, Alkermes
Julia Hoar, AstraZeneca
Stew Hoover, UCB
Darren Keegan, Allergan
Brad Martin, Lundbeck
Kim McCafferly, AstraZeneca
John Meyer, Otsuka America
Dennis Oralls, Eisai
Hannah Parker, AstraZeneca
Jai Persico, Otsuka
Lance Nicholls, Pfizer
Jim Pitt, Lundbeck
Wendy Pollinger, Eli Lilly
George Small, AstraZeneca
Gillian Stephens, AstraZenca
Scott Williams, J&J

Joseph Lasek, MD, Chair, called the meeting to order at 6:50 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:00 p.m. until 6:40 p.m.

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The September meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Nancy Hogue, PharmD, DVHA

- Welcomed the two new members of the DUR board, Patrica King, MD and Zail Berry, MD.

- This is Dr. Joseph Lasek's MD last meeting and a new chair will be elected at the December meeting.
- Legislative annual report on Best Practices and Cost control was recently completed. The format of the report has been updated and now contains more information regarding new drugs coming into the market. Currently the report is in internal review and should be available for external review by the end of October. A link will be sent when published on the web.

4. Medical Director Update: Scott Strenio,MD, DVHA

- No update at this time.

5. Follow-up Items from Previous Meetings: Dr. Thomas Simpatico, MD, DVHA

a) Vivitrol Criteria

- Vivitrol (naltrexone for extended-release injectable suspension) will be made more available to providers in the state. Guidelines will be placed to ensure consistency throughout the state regardless of where a patient starts treatment. Patients who are started on Vivitrol should have at least a one week exposure to oral naltrexone. There are no changes to the current criteria at this time.

Recommendation: None at this time.

Board Decision: None required.

6. Retro DUR/DUR: Dr. Jeff Barkin GHS/Emdeon

a) Present data testosterone therapy

There is a general clinical consensus that testosterone replacement therapy in patients who are clearly deficient can help alleviate symptoms. There is also general consensus that testosterone therapy be limited to those with documented low testosterone levels in association with signs and/or symptoms. Guidelines recommend total testosterone levels be measured at baseline, 2-3 months after initiation, and 6 - 12 months to ensure the level is stable. Due to the risk of polycythemia, a CBC is recommended pre-treatment, after 2-3 months of therapy and annually.

GHS reviewed Vermont medical claims data from 6/30/2013 through 10/1/2015 which indicated that many patients are not getting the recommended screening. The medical claims data revealed that 1 in 5 patients treated were not getting baseline testosterone levels or labs prior to treatment. The percentage of members after 1 year of treatment with no follow up labs was calculated to be 16%. Medical claims data may be unreliable as there may be a proportion of patients that have been covered by other payors (third pary liability). Additionally, claims data may not have included every combination of codes to capture the specific studies.

Recommendation: The recommendation is to preform a chart review of a randomized sample of patient records.

A board member recommended using a rank ordering system of providers on the basis of prescribing rates and offer targeted direct feedback.

Board Action: The Board approved the above recommendation of using a rank ordering system to identify physicians that were most often prescribing Testosterone.

7. SSDC/PDL 2016 Changes

Majority of changes will be voted on in the December meeting. Criteria for those changes will be reviewed at the December meeting. Limited brand to generic changes are being voted on in this meeting.

- Anticonvulsants
  - Recommended change for Trileptal® Suspension to be moved to the non-preferred position on the Preferred Drug List (PDL).
  - Recommended to change generic Oxcarbazepine oral suspension to the preferred position on the PDL.
  - Recommended to remove Stavzor® from the PDL , no longer available.

  The Board unanimously approved the above recommendations

- Corticosteroid Intranasal
  - Recommended to remove Nasonex ® nasal spray from the PDL, availability issue.
  - Recommended to change Omnaris® and Zetonna® HFA to the preferred position on the PDL.

The Board unanimously approved the above recommendations

- Anti-infective/Antifungals
  - Recommended to change Terbinafine tablets to the preferred position on the PDL.
  - Recommendation to change Griseofulvin to the non-preferred position on the PDL.

  The Board unanimously approved the above recommendations

- Antifungals: Onychomycosis
  - Recomendation to change Ciclopirox 8% solution to preferred agent.
  - Recommendation to add documented intolerance to generic Ciclopirox for approval of Jublia®, Kerydin®, and Penlac®.

  The Board unanimously approved the above recommendations

- **Antihypertensives**
  - To be reviewed in the class review

8. Clinical Update: Drug Reviews:

Abbreviated New Drug Reviews

a) Brilinta®Tab (ticagrelor)

Recommendation: PDL placement and criteria will be recommended when the Therapeutic Class Review (TCR) is examined.

Public Comment: No public comment.

Board Decision: Defer decision - to occur with the class review

Full New Drug Reviews: Mike Ouellette, RPh, GHS/Emdeon & Jeffrey Barkin, MD GHS/Emdeon

a) Corlanor® Tab (ivabradine)

- Indicated for symptomatic treatment of chronic angina in patients who cannot take beta blockers. Spontaneous firing of pace maker activity is decreased through the inhibiton of the hyperpolarization-activated cyclic nucleotide-gated channels (f-channels) within the sinoatrial (SA) node.The most common side effect is bradycardia.

- The Shift Trial demonstrated decrease risk of hospitalization (NNT = 24). There is no significant data to support clinical improvement or decreased morbidity and mortality.

Recommendation: The recommendation is to expand the PDL category of coronary vasodilators and antianginals to include Sinus Node inhibitors. The recommendation is to add Corlanor® to the non-peferred side of the PDL.

Clinical Criteria:

- Diagnosis of Stable Symptomatic heart failure.
- LVEF < 35%.
- Resting HR > 70 bpm.
- Persisting symtpoms despite maximumally tolerated doses beta blockers.
- Contraindication to beta blocker therapy.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

b) Cresemba® Cap (isavuconazonium sulfate)

Indicated for the treatment of invasive aspergillosis. It is a prodrug of Isavuconazonium - an azole antifungal that inhibits the synthesis of fungal cell walls. A randomized double blinded trial showed Cresemba was non inferior to the preferred regimen of Voriconazole for the treatment of invasive aspergillosis. Cresemba® may also be used in treatment of invasive mucormycosis.

Recommendation: The recommendation is to add Cresemba® to the non-preferred side of the PDL. Clinical Criteria:

- Diagnosis of either invasive aspergillosis or mucormycosis.
- Age > 18 years old.
- Documented side effect, allergy, contraindication or treatment failure with voriconazole
- Completion of regimen started by hospital.
- Additional changes to the criteria recommended for the category included:
    - Removal of Oravig from the PDL as it is no longer available.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Namzaric® Cap (donepezil and memantine)

- Is included in the Therapeutic Class Review and is a combination of donepezil and memantine, both of which are generically available.

Recommendation: PDL placement and criteria will be recommended when TCR is reviewed.

Public Comment: No public comment.

Board Decision: Defer decision - to occur with the class review.

d) Natesto® Gel (testosterone)

- Indicated for the treatment of primary hypogonadism due to the treatment of Klinefelter Syndrome, chemotherapy, etc. The safety and efficacy has been established in men > 18 years old. Testosterone levels and CBC should be obtained at baseline and after initiation of Natesto® to minimize the risk of side effects such as polycythemia. A trial showed that Natesto® was able to return men to a normal baseline testosterone level.

Recommendation: Recommendation is to add Natesto® to the non-preferred side of the PDL .

Clinical Criteria:

- Documented contraindication or treatment failure with Androgel.
- Additional changes to the criteria recommended for the category include:
  - Removal of criteria requiring the use of testosterone pump for non-preferred agents.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

e) Natpara® (Parathyroid hormone)

- Indicated for the treatment of hypocalcemia in patients with hypoparathyroidism in patients who were unable to be successfully treated with calcium and vitamin D supplements. Natpara is produced by recombinant DNA technology using a modified strain of Escerichia coli. Parathyroid hormone raises serum calcium concentrations by increasing renal tubular calcium reabsorption, increasing intestinal calcium absorption, and by increasing bone turnover. Natpara® is dosed based on the lowest dose needed to achieve an appropriate total serum calcium; there is a dose and duration related risk for the development of osteosarcoma when exposed to parathyroid hormone. Studies have shown that for every two people treated with Natapara®, one will achieve a normal calcium level.

Recommendation: The recommendation is to create a new PDL category for parathyroid agents. Natapara® would be added to the non-preferred side of the PDL.

Clincial Criteria:

- For patients with hypocalcemia secondary to hypoparathyroidism.

- For patients whose hypocalcemia is unresponsive to active vitamin D and calcium supplements.
- Quantity limit = 2 cartridge per 28 days.

Public Comment: No public comment.

Board Decision: The board unanimously approved Natpara® to be placed in the non-preferred position on the PDL. The board has requested additional information regarding clinical criteria and GHS will bring to December meeting.

f) Nuvessa® Gel (metronidazole gel)

- Indicated for the treatment of bacterial vaginosis. In a randomized double blinded treatment Nuvessa® showed improvement in both clinical and therapeutic cure when compared to vehicle gel only.

Recommendation: The recommendation is to add Nuvessa® to the non-preferred position on the PDL for patients with a documented contraindication or treatment failure to generic metronidazole or vandazole vaginal gel .

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

g) ProAir Respiclick® Inhal (albuterol)

- Indicated for the treatment or prevention of bronchospasm in patents > 12 years old. ProAir Respiclick® is another device used to administer Albuterol, a beta-2 agonist. Short acting Beta agonists are recommended as first line therapy by The National Heart, Lung, Blood Institute Guidelines.

Recommendation: The recommendation is to add ProAir Respiclick® to the non-preferred position on the PDL.

Clinical Criteria:

- Documented side effect, allergy, or treatment failure to ONE preferred short acting metered dose inhaler.
- Additional changes to the criteria recommended for the category included:

Removal of Brethine® and Accuneb® from the PDL due to unavailability.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

9. Therapeutic Drug Classes- Periodic Review: Mike Ouellette, RPh, GHS/Emdeon and Jeffrey Barkin, MD , GHS/Emdeon

a) Alzheimer's Agents

- Namzaric®, a new drug in this category which is a comination of Donepezil and Memantine to provide patients with a single agent.
- Namzaric® is indicated for the treatment of Alzheirmer's in patients with moderate to severe Alzheimer dementia. Namzaric® is a combination of donepezil and memantine. The combination of donepezil and memantine is used in patients to stabilize and improve Alzheimer symtpoms and dementia. Cholinesteraste inhibitors, such as donepezil, increase cholinergic effects by inhibiting acetylcholinesterase to help reverse or slow the progression of cognitive deficits. Donepezil was statistically significant in improving memory compared to placebo; however, these results are not mirrored clinically. Memantine is a low-affinity voltage dependent uncompetitive antagonist at the glutamatergic N-methyl-D-aspartate (NMDA) receptors, located throughout the brain. Excessive receptor activation, as thought to occur during Alzheimer's disease, results in a chronically open state and excessive calcium influx. Inhibiting calcium induced toxicity which causes brain cell death can help support the nervous systems of patients with Alzheimer's.

Recommendation: The recommendation is to add Namzaric® to the non-preferred side of the PDL.

Clinical Criteria:

- Clinically compelling evidence against use of individual agents
- Quantity Limit = 1 capsule/day.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

b) Angiotensin Modulators

- No clinically significant changes.

Recommendation: No changes recommended to the category or criteria, however it was suggested that Micardis®/Micardis ®-HCT move to the preferred position on the PDL and generic telmisartan/ telmisartan-HCT to non-preferred due to cost considerations.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Beta Blockers

- No clinically significant changes.

Recommendation: No changes recommended to the category or criteria, however it was suggested that Innopran XL® move to the preferred position on the PDL and generic propranol ER to the non-preferred position on the PDL due to cost considerations. Other recommended changes to the PDL include: 1. Adding Hemangeol®(propranolol oral solution) and Sorine to the non-preferred position on the PDL. 2. Moving timolol to the non-preferred position on the PDL. 3. Moving the combination beta blocker/diuretic products nadolol/bendroflumethiazide and Dutoprol® to the non-preferred position on the PDL.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) CCBs

○ No clinically significant changes.

Recommendation: The recommendation is to add amlodipine-valsartan-HCTZ to the preferred position of the PDL and to remove drugs that are no longer available, Cardene®, Nimotop®, Dynacirc® ,Covara-HS®, Isoptin®, Isoptin® SR, Dilacor®, and Dilacor®XR.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

e) ACE Inhibitors

○ No clinically significant changes.

Recommendation: The recommendation is to add trandolapril-verapamil HCl ER to the preferred position of the PDL in the ACE-Inhibitor/CCB sub-category. It was also recommended to remove Prinzide® and Uniretic® from the PDL due to unavailability.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

f) Lipotropics, Other Non-Statins

○ Zetia® has been a non-preferred agent because of lack of data showing clinical benefit. The IMPROVE-IT Trial, published in 2014, showed improvement in cardiovascular outcomes in patients who received a combination of both simvastatin and Zetia®compared to high doses of simvastatin monotherapy.

○ New agents such as Proprotein convertase subtilisin/kexin type 9 (PCSK-9) inhibitors, Praluent® and Repatha®, work by inhibiting PCSK-9 actions on LDL receptors on the

surface of the hepatocytes, increasing the elimination of LDL by the liver. Both agents are indicated to be used in combination with high dose statins for patients who need further reduction of LDL despite maximum statin therapy and lifestyle modifications. Praluent® and Repatha® are both given subcutaneously.

Recommendation: No recommendations at this time; will be discussed in more detail at subsequent meeting.

Public Comment: No public comment.

Board Decision: None required.

g) Lipotropics Statins

○ No clinically significant changes

Recommendation: It is recommended to keep the current criteria and remove Juvisync from the PDL due to unavailability.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

h) Platelet Aggregation Inhibitors Intermittent Claudication

○ The only drug in this category is Brilinta® (ticagrelor). PEGASUS-TIMI 54 trial studied the prevention of thrombic events in patients with Acute Coronary Synrome. Brilinta® was administered with ASA to the treatment group and compared to a group receiving clopidogrel and ASA. The study demonstrated a reduction in composite endpoints in patients of the treatment group. Patients taking Brilinta had fewer atherosclerotic events and heart attacks.

Recommendation: The recommendation is to add aspirin-dipyridamole ER to the non-preferred side of the PDL. Brilinta® will be discussed further at the December meeting.

Public Comment: In a letter submitted to the Board, Dr. Prospero Gogo, MD stressed the benefit of Brilinta over clopidogrel and would like it to be placed in the preferred position on the PDL to mirror guidelines and recommendations. Gillian Stephens, AstraZenca : Highlighted some of the attributes of Brilinta®.

Board Decision: The Board unanimously approved the above recommendations.

10. New managed Therapeutic Drug Classes

- None at this time.

11. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products

- None at this time.

12. General Announcements Mike Ouellette, RPh, GHS/Emdeon

- Selected FDA Safety Alerts
  - Non-aspirin Nonsteroidal Anti-inflammatory Drugs (NSAIDs): Drug Safety Communication - FDA Strengthens Warning of Increased Chance of Heart Attack or Stroke

    http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm454141.htm

  - Unapproved Prescription Ear Drop (Otic) Products: Not FDA Evaluated for Safety, Effectiveness and Quality

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453430.htm

  - Codeine Cough-and-Cold Medicines in Children: Drug Safety Communication - FDA Evaluating Potential Risk of Serious Side Effects

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm

  - FDA Issues the Drug Supply Chain Security Act (DSCSA) Implementation: Product Tracing Requirements for Dispensers–Compliance Policy Guidance

http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm

  - FDA Drug Safety Communication: FDA reporting permanent skin color changes associated with use of Daytrana patch (methylphenidate transdermal system) for treating ADHD

http://www.fda.gov/Drugs/DrugSafety/ucm452244.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

  - Brintellix (vortioxetine) and Brilinta (ticagrelor): Drug Safety Communication - Name Confusion

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm

  - Picato (ingenol mebutate) Gel: Drug Safety Communication - FDA Warns of Severe Adverse Events, Requires Label Changes

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm459311.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

- No action required.

13. Adjourn: Meeting adjourned at 8:32 p.m.